REMARKS

Reconsideration of the subject patent application in light of the present Amendment and Remarks is respectfully requested.

This amendment has been made to put this application in condition for immediate allowance.

Claims 4 to 7, 10 to 22 and 26 remain withdrawn from consideration without prejudice to Applicant's right to pursue the subject matter of these claims in a future continuation application.

Claims 1 to 3 and 8 to 9 have been canceled without prejudice to Applicant's right to pursue the subject matter of these claims in a future continuation application.

Claims 23 to 25 have been amended to more clearly point out that the claims as amended are directed at a daily dosage of the composition. Support for the amendment is found at, for example, page 5, lines 27-34 and Tables 1, 2 and 5.

Claims 23 to 25 have also been amended according to the suggestion of the Examiner to include a pharmaceutically acceptable carrier. Support for this amendment is found at, for example, original claim 9 of the application.

Claim 25 has additionally been amended in accordance with the Examiner's request to conform to the listing found in Table 5. As a result, the range for lipoamide has been amended to 0.01 to 100.0 mg and daily dosages of calcium and manganese in the range of 0.01 to 10.0 mg have been added. Support for these amendments is found, for example, in Table 5.

Entry of this Amendment is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 23 to 25 have been rejected under 35 U.S.C. §112, first paragraph, for lack of written description. The Examiner states that there is: (1) no basis or support for the recited amounts "of a daily dosage;" (2) no correlation between the recited ranges and "daily dosage;" and (3) "daily dosage" is an administration limitation that is inconsistent with a

composition claim. The Examiner additionally states that there is no basis or support for the composition claimed in claim 25 consisting of certain ingredients.

Applicant respectfully requests reconsideration and withdrawal of this rejection because, as set forth more fully below, support for a "daily dosage" of the listed substances in the recited ranges is found in the specification at, for example, page 5, lines 29-32, which teaches a daily intake of metabolic compounds in the Krebs cycle (claims 23 and 24) along with cofactors (claim 25). Furthermore, the claimed compositions and dosage ranges are found in Tables 1, 2 and 5.

The daily dosage element of claims 23 to 25 is fully supported by the "daily intake" disclosure of the application

The application provides support at page 5, lines 27-32, for a daily dosage of metabolites of the Krebs cycle, as claimed in claims 23 and 24, and for cofactors to the enzymes related to the Krebs cycle, as claimed in claim 25. There, the application discloses to the artisan:

> The present invention provides a method and composition for compensating . . . deficiencies in bioenergy metabolism by administering . . . lacking biochemical components to the body. The daily intake of the metabolic compounds of the Krebs cycle is further enhanced by . . . cofactors for the enzymatic reaction in this cycle.

(emphasis added). Three paragraphs later, the artisan is instructed: "Preferably, the present invention relates to biochemical substances of the Krebs cycle . . . as shown in Table 1 . . . ." Table 1 immediately presents the compounds and dosages now claimed in claim 23.

Two paragraphs thereafter, the specification discloses: "Preferably, the present invention relates to biochemical substances of other intermediate steps of the Krebs cycle as shown in Table 2 . . . ." Table 2 then immediately presents the compounds and dosages now claimed in claim 24. From this extensive disclosure, there can be no doubt that the ranges of Tables 1 and 2 are provided as a possible regimen of daily intake of metabolites of the Krebs cycle and that claims 23 and 24 are directed at the very disclosed ranges.

There is, further, no doubt that the cofactors of Table 5 are additionally provided as a possible regimen for daily intake, either in a combination with other cofactors or in

combination with other metabolites of the Krebs cycle. On page 5 at lines 27 to 34 the specification teaches:

> The present invention provides a method . . . for compensating . . . deficiencies in bioenergy metabolism . . . . The daily intake of the metabolic compounds of the Krebs cycle is further enhanced by . . . cofactors for the enzymatic reaction in this cycle. Optimum supply of these coenzymes can compensate – at least in part – for the insufficient availability of the enzyme itself . . . .

As a result, the artisan understands that a daily dose of the cofactors of the invention is useful in improving bioenergy metabolism.

The artisan's understanding is further enriched in section (d) of the specification, which is entitled "The Cofactors of Cellular Energy Metabolism." In section (d), the artisan is instructed:

> [D]eficiencies of the biochemical components of the cellular metabolism may be a causative or contributing factor to the pathology of disease [and the] present invention provides a method and composition for compensating such deficiencies in the cellular metabolism by administering such lacking biochemical components to the body.

Appln. at 9, lines 15-20 (emphasis added). In the second paragraph thereafter, the specification continues to teach: "Preferably, the present invention provides cofactors which enhance enzymatic reactions of metabolism . . . ." Appln. at 10, lines 3-5. Table 5 then immediately provides cofactors and dosages to support the function of the Krebs cycle.

The specification, therefore, teaches: (1) "[t]he daily intake of the metabolic compounds of the Krebs cycle is further enhanced by . . . cofactors," (2) deficiencies in cofactors may be the "caus[e]" of disease, (3) "coenzymes can compensate . . . for the insufficient availability of enzymes," and (4) Table 5 "provides cofactors which enhance enzymatic reaction of metabolism." In view of this disclosure, the artisan is left with the unmistakable understanding that the dosages of Table 5 are provided as a possible daily regimen to enhance the body's own Krebs cycle metabolites or to enhance those Krebs cycle metabolites provided in a daily supplement. In either teaching, the full scope of claim 25 is fully supported.

In sum, a thorough review of the specification leaves the artisan with no doubt that the ranges of Tables 1 and 2 are provided as a possible regimen of daily intake of metabolites of the Krebs cycle and that the ranges of Table 5 are provided as a possible regimen of daily intake of cofactors to support the function of metabolites in the Krebs cycle. As a result, the "daily dosage" language of claims 23 to 25 is fully supported by the specification.

Gentry Gallery and *Purdue Pharma* are not contrary to written description support of claims 23-25.

The Examiner has raised *Gentry Gallery v. Berkline,* 45 USPQ2d 1498, for the proposition that Applicant may not broaden the claimed invention without support in the as-filed specification. Applicant respectfully asserts that, in light of the discussion above, Applicant has not broadened the claimed invention, but instead has provided claims plainly in line with the unambiguous disclosure of a daily dose of the compounds in the claimed ranges.

The Examiner has also raised *PurduePharma v. Faulding* 56 USPQ2d 1481 for the proposition that a narrow ratio that falls within a broad disclosure but, which Applicant did not disclose as part of the invention, may not be claimed. The opposite is the case here—the exact ratio disclosed in the specification as appropriate for a daily dose is claimed in claims 23 to 25, as amended.

Preamble language such as "daily dosage" is plainly acceptable under current case law

The Examiner has additionally stated that the recitation of "daily dosage" is an administration limitation that is inconsistent with a composition claim. Claims 23 to 25, as amended, should obviate the Examiner's objection. Furthermore, Applicant respectfully traverses the Examiner's opinion. In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). Conversely, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention. *Id.* A preamble may add life and vitality even to a composition claim. *See In re* Gardner, 171 F.2d 313 (CCPA 1948). Here, the "daily dosage" language of the preamble, as amended, provides the claims with more than just an intended use and therefore defines the scope of the

claims as more than a simple composition. In view of the law on this subject, Applicant respectfully requests the Examiner withdraw this reason for rejection of claims 23 to 25.

Claim 25 has been amended to conform with Table 5

The Examiner has additionally rejected claim 25 because the range of 0.01 to 20.0 mg of lipoamide does not conform with the range of 0.01 to 100.0 mg contained in Table 5 and the claim does not contain calcium as contained in Table 5. Applicant has amended claim 25 in accordance with the Examiner's request and has additionally added manganese in the range of 0.01 to 10.0 mg to fully conform claim 25 with Table 5. Nevertheless, Applicant respectfully traverses the Examiner's opinion that claim 25 must conform with Table 5 to satisfy the written description requirement. The specification teaches throughout that each compound of the disclosed compositions plays a role in improving bioenergy metabolism of cells. *See, e.g.*, Appln. at 2-3 (repeating for each class of compounds, "a composition to improve bioenergy . . .comprising two or more chemical substances . . . .").

Rejection under 35 U.S.C. § 112, second paragraph

Claims 23 to 25 have been rejected under 35 U.S.C. §112, second paragraph, for indefiniteness. As suggested by the Examiner, Applicant has amended claims 23 to 25 to encompass a pharmaceutical carrier for the composition of the claims. Applicant, therefore, requests the Examiner withdraw this rejection.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claim 1 under 35 U.S.C. § 103(a). The claim has been canceled. Applicant requests the Examiner withdraw this rejection.

CONCLUSION

Applicant believes this Application is now in condition for allowance and such action is respectfully requested. If for any reason the Examiner believes contact with the Applicant's attorney would advance the prosecution of this application, the Examiner is invited to contact the undersigned at the number given below.

Respectfully Submitted,

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